

REMARKS

This Response is submitted in reply to remarks made in the Advisory Action, mailed October 24, 2008.

Failure to Enter the Amendment

In the Action, the Examiner fails to enter the Amendment After Final Office Action of September 25, 2008, reasoning that the amendments made in the Amendment After Final Rejection do not place the application in better form for appeal. Applicants submit that the Amendment After Final Rejection does in fact place the application in better form for appeal. IN support of this, Applicants submit that the Amendment contains terminal disclaimers which obviate the obviousness type double patenting rejections over claims 1-4, 7-10 and 12-13 of U.S. Patent no. 6,855,690, and over claims 1 and 2 of U.S. Patent no. 7,238,529. In addition to this, the Amendment cancels claim 22, which obviates the rejection under 35 USC 102(b) as anticipated by Sherman et al. By eliminating these two outstanding rejections, the Amendment materially reduces the issues for appeal, and as such places the application in better form for appeal. Further, the cancellation of all pending claims and addition of new claims 34-38 in the Amendment removes the treatment aspect of the prior claims, which was the Examiner's only stated concern regarding enablement of the claims by the specification, discussed further below. As such, entry of the Amendment would further place the application in better form for appeal.

Failure to Allow Claims

In the Advisory Action, the Examiner indicates that new claims 34-38, submitted in the Amendment After Final Office Action of September 25, 2008, recite the same limitations that were rejected earlier, and because of this, the rejection under 35 USC 112, first paragraph (lack of an enabling specification) is maintained. Applicants submit that this statement is incorrect. Previously rejected claims were drawn to methods of treatment of neurological disorders comprising administering a therapeutically effective amount of a hexose to a subject. New claims however recite "a method of promoting neuronal outgrowth in a neuron comprising contacting the neuron with D-mannose". Support for the previous rejections made under 35

USC 112, first paragraph, (lack of enablement) has centered on the lack of enablement of the specification for treating the stated neurological disorders. More specifically, Examiner Krishnan has stated the following in support of his rejection of claims 1-26 as non-enabled by the specification:

“the specification, while being enabling for the regeneration of axons on retinal ganglion cells by administration of mannose and forskolin and a composition comprising mannose and a pharmaceutically acceptable carrier, does not reasonably provide enablement for the treatment of any neurological disorder as broadly claimed in instant claim 1 and all the disorders recited in claims 10-11, 18-22 and composition claims 23-26.” (Office Action of 11/21/07, page 2, last paragraph)

“one of ordinary skill in the art would not extrapolate the information in the prior art to the treatment of all of the said diseases and conditions.” (Office Action of 11/21/07; page 4, lines 1-2)

“With different etiologies for several and unknown causes for some diseases it is highly unpredictable that administration of a hexose like mannose or gulose or glucose-6-phosphate either alone or in combination with a cAMP modulator like oncomodulin or TGF- β can treat any and all of the disorders as instantly claimed.” (Office Action of 11/21/07, page 4, lines 9-13)

“The instant specification is not seen to provide enough guidance that would allow a skilled artisan to extrapolate from the disclosure and the examples provided to enable the treatment of all the neurological disorders as instantly claimed. The specification also fails to direct the skilled artisan in correlative prior art procedures which might provide the basis for the said treatment” (Office Action of 11/21/07, page 4, lines 15-19)

“The working examples set forth in the instant specification are drawn to the effect of mannose and mannose forskolin combination on rat ganglion cells. The results just show the growth of axons regeneration. Despite these examples there is little enabling disclosure for the treatment of all of the neurological disorders as instantly claimed. Applicant has given working examples of the effect of the compounds on rat ganglion cells only. Based on this one of ordinary skill in the art cannot predict or extrapolate it to the treatment of all the diseases and conditions as instantly claimed. The growth of axons alone cannot treat all of the disorders as instantly claimed.” (Office Action of 11/21/07, page 4, last two lines through page 5, line 6)

"... the instant disclosure is not seen to be sufficient to enable the use of the instant compounds for the treatment of neurological diseases as instantly claimed. One of ordinary skill in the art would have to carry out experimentation with several different disorder models in order to determine the efficacy of the said compounds in the said methods of treatment." (Office Action of 11/21/07, page 5, lines 9-13)

The above quoted passages comprehensively represent the concerns of the Examiner regarding the rejection of cancelled claims 1-31 under 35 USC 112, first paragraph (enablement) made in previous Office Actions. Pending claims 34-38 are not directed to methods of treatment of neurological disorders and as such do not recite the same limitations that were rejected earlier. Further, pending claims 34 -38 recite language specifically suggested by the Examiner in a phone interview with Applicant's attorney, August 20, 2008. In light of this, Applicants respectfully request reconsideration of the pending claims.

In view of the amendments to the claims made in the Amendment filed September 25, 2008, and the arguments presented therein and above, Applicants respectfully submit that the claims are now in condition for allowance.

The Commissioner is authorized to charge any fees and credit any overpayments that may be due in connection with this submission to Nixon Peabody LLP Deposit Account No. 50-0850.

Date: October 27, 2008

Respectfully submitted,

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